Defining "How Clean Is Clean"

- Exposure data collection
- Epidemiology
- Analytical
- Toxicology

clean /klin/ [kleen]
adjective, -er, -est.
adverb, -er, -est

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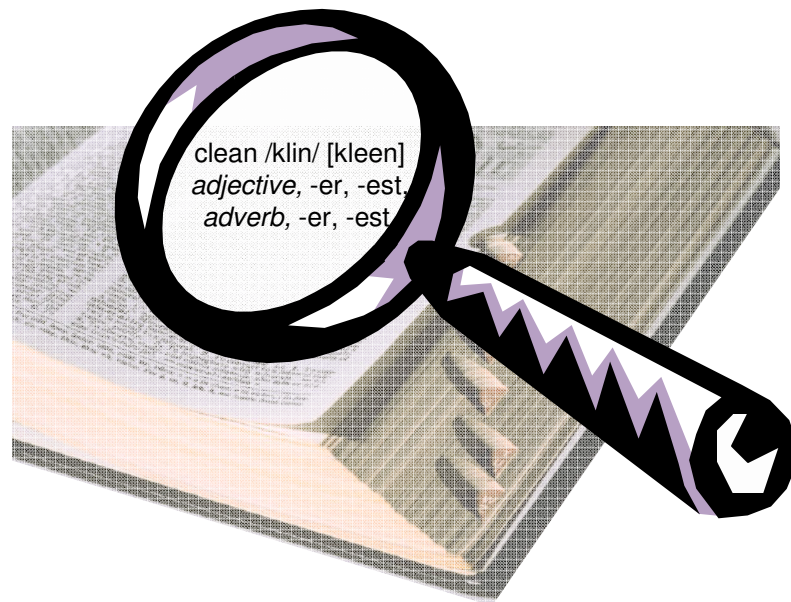
Sampling and Analytical Studies to Support Baseline Risk Assessment

Analytical
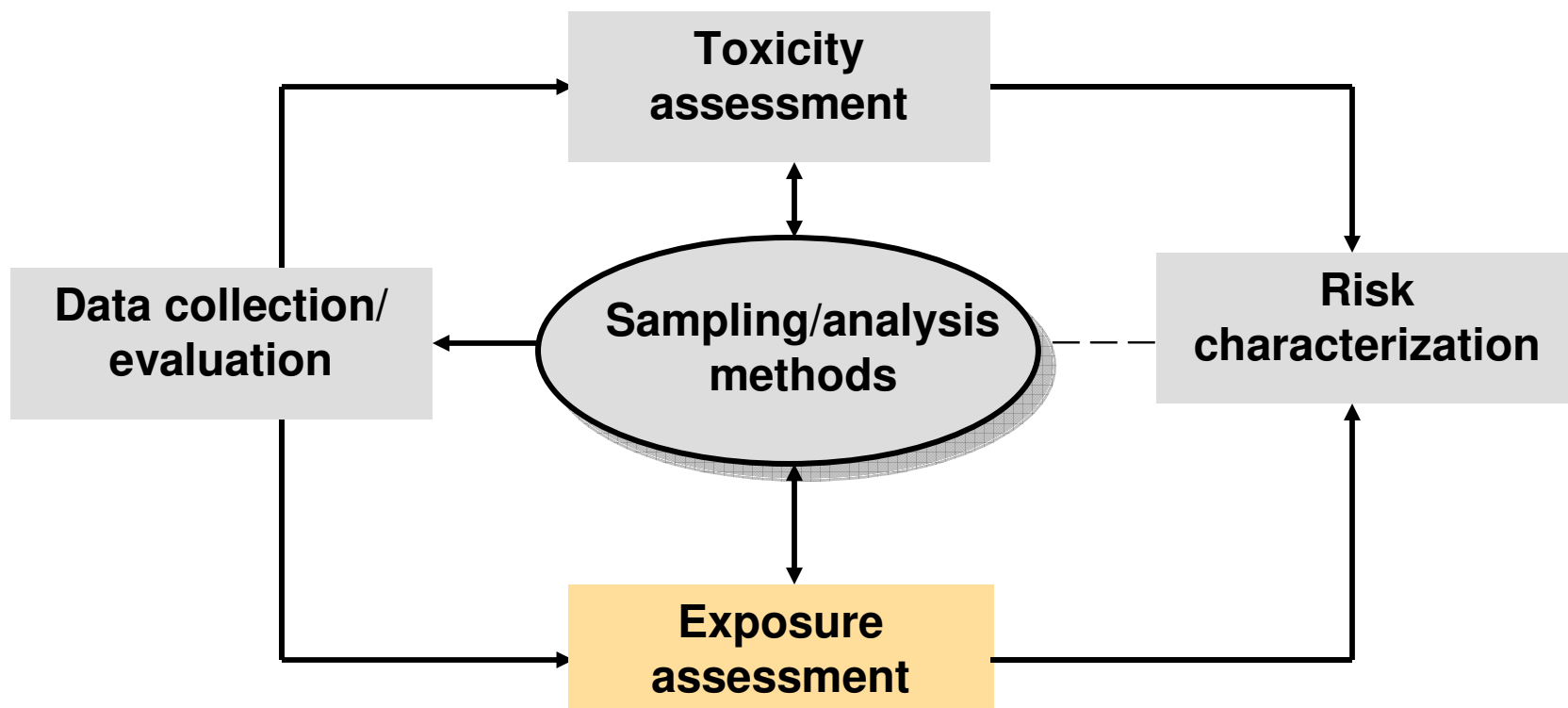
Critical Exposure Data Issues

1. Solid matrix sampling insufficient for cleanup decisions

2. Completed exposure pathways in the Conceptual Site Model (CSM) are not properly quantified

3. Current cleanup efficacy not yet evaluated

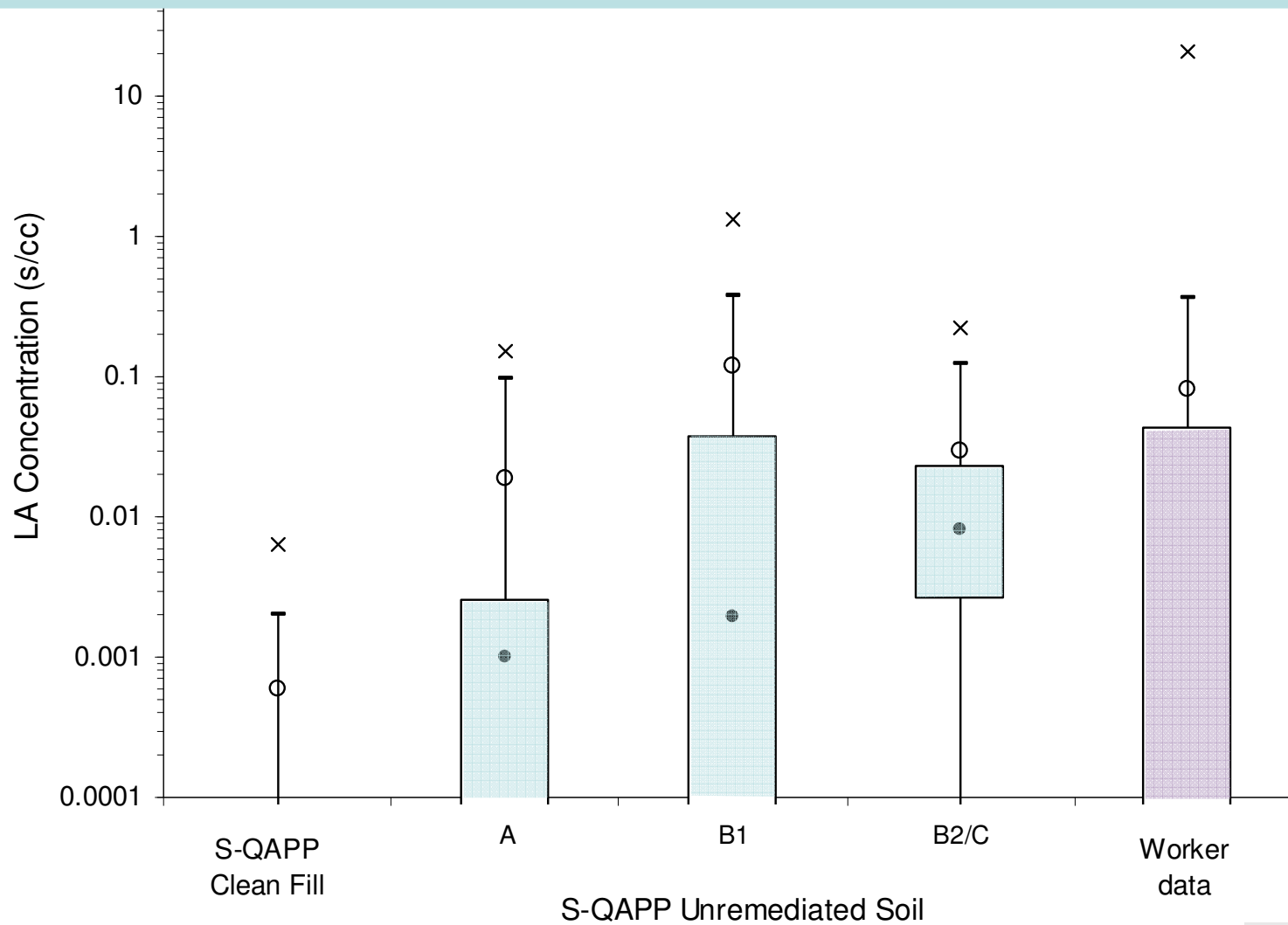4. Nature and extent data are not complete for the mine and Troy (traditional RI)

Exposure

Solid Matrix Sampling

Challenges

- Soils that are non-detect by PLM still generate significant airborne fibers when disturbed

- Relationship between Libby Asbestos contamination of indoor dust to indoor air is poorly understood
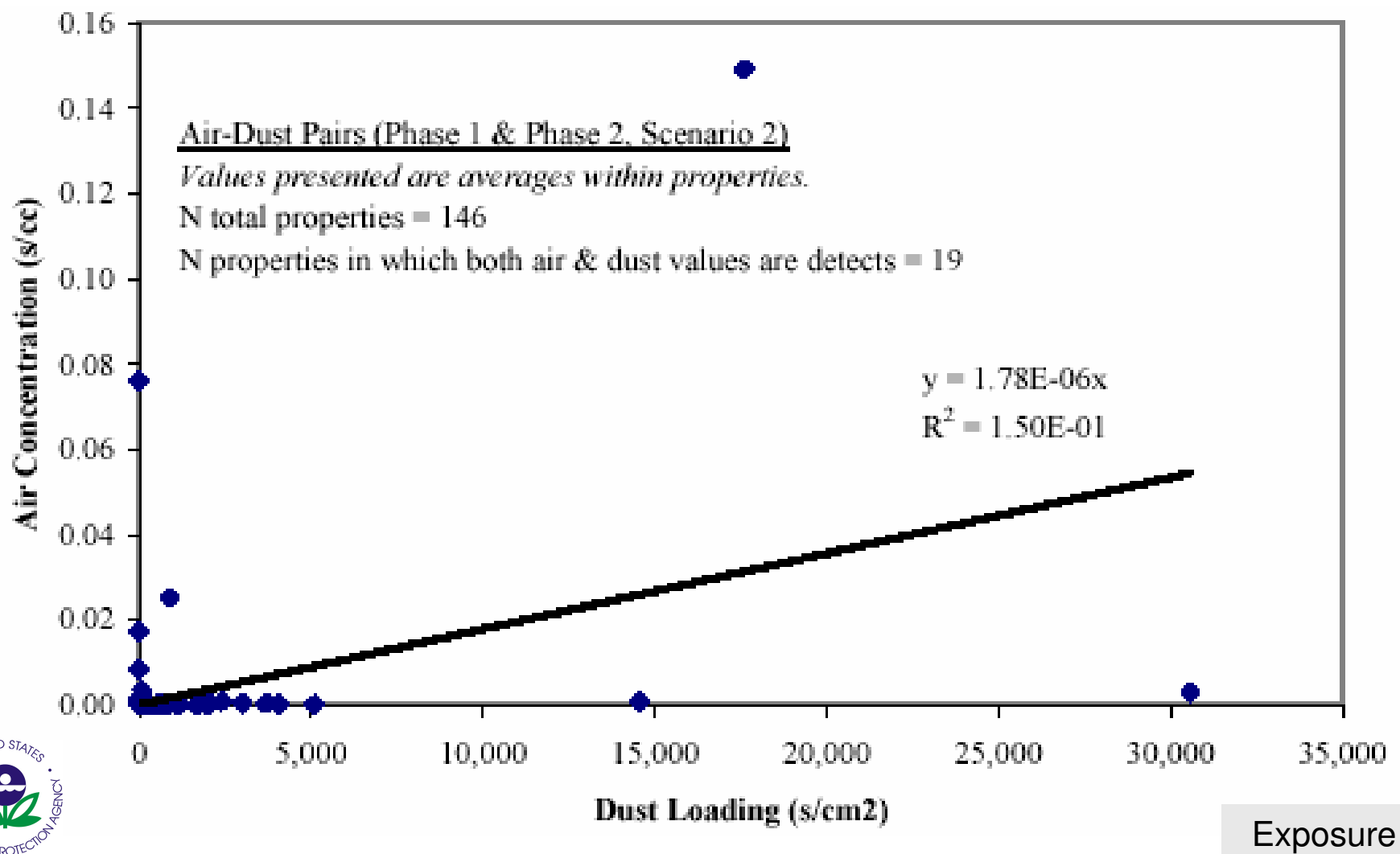
Preliminary ABS Results

Indoor Dust to Indoor Air

Air-Dust Pairs (Phase 1 & Phase 2, Scenario 2)
Values presented are averages within properties.
N total properties = 146
N properties in which both air & dust values are detects = 19

$y = 1.78E\text{-}06x$
$R^2 = 1.50E\text{-}01$

Air Concentration (s/cc)

Dust Loading (s/cm2)

Exposure

Combined CSM/Efficacy Sampling

- The "Big Three" pathways
  - Outdoor ambient air
  - Indoor air (ABS)
  - Outdoor air around contaminated soils (ABS)
- Transportation corridors
- The rest

Exposure

Nature and Extent

- Mine
  - Extent of soil contamination
  - Stream transport
  - Airborne transport
  - Surrounding trees
- Troy
  - How many properties impacted

Exposure

Current Epidemiologic Investigations

- **Libby Workers**
  - NIOSH 2007: Updated mortality study
  - ATSDR X-ray study for disease progression
- **Marysville Workers/Household Contacts**
  - NIOSH study of exposure & non-cancer lung effects (RfC)
  - Univ of Cincinnati: X-rays, lung function, and mortality studies
- **EPA coordinated evaluation of data**
  - Develop site-specific RfC
  - Consideration of non-respiratory ailments
  - Identify potential biomarkers

Epidemiology = Study of Disease in Human Populations

Proposed Epidemiologic Studies
Libby, MT and Marysville, OH

- Compile & analyze data from all studies to assess
  - Exposure-response relationships
  - Disease process

- New and better medical testing of workers and others
  - Includes kids and susceptible populations
  - More sophisticated tests
  - Improves understanding of
    - Risk factors for disease
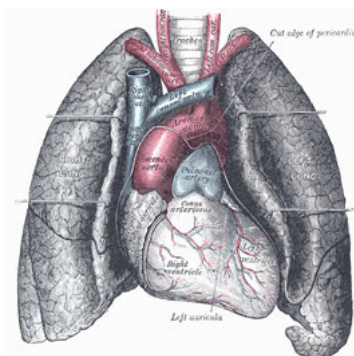   - Exposure-response relationship
    - Disease process

Note: Any studies involving human research will be subject to prior review and approval by a qualified Human Subjects Review Board

Epidemiology

Medical Surveillance & Tissue Studies

- Ongoing medical testing of select groups to
  - Improve understanding of health effects over time
  - Help determine if clean ups are working
  - Help identify biomarkers of exposure or disease
  - Provide a platform for treatment/disease prevention work

- Study of Libby Amphibole in human lung tissue to
  - Help understand how and where fibers are causing disease
  - Characterize fibers in human lung tissue
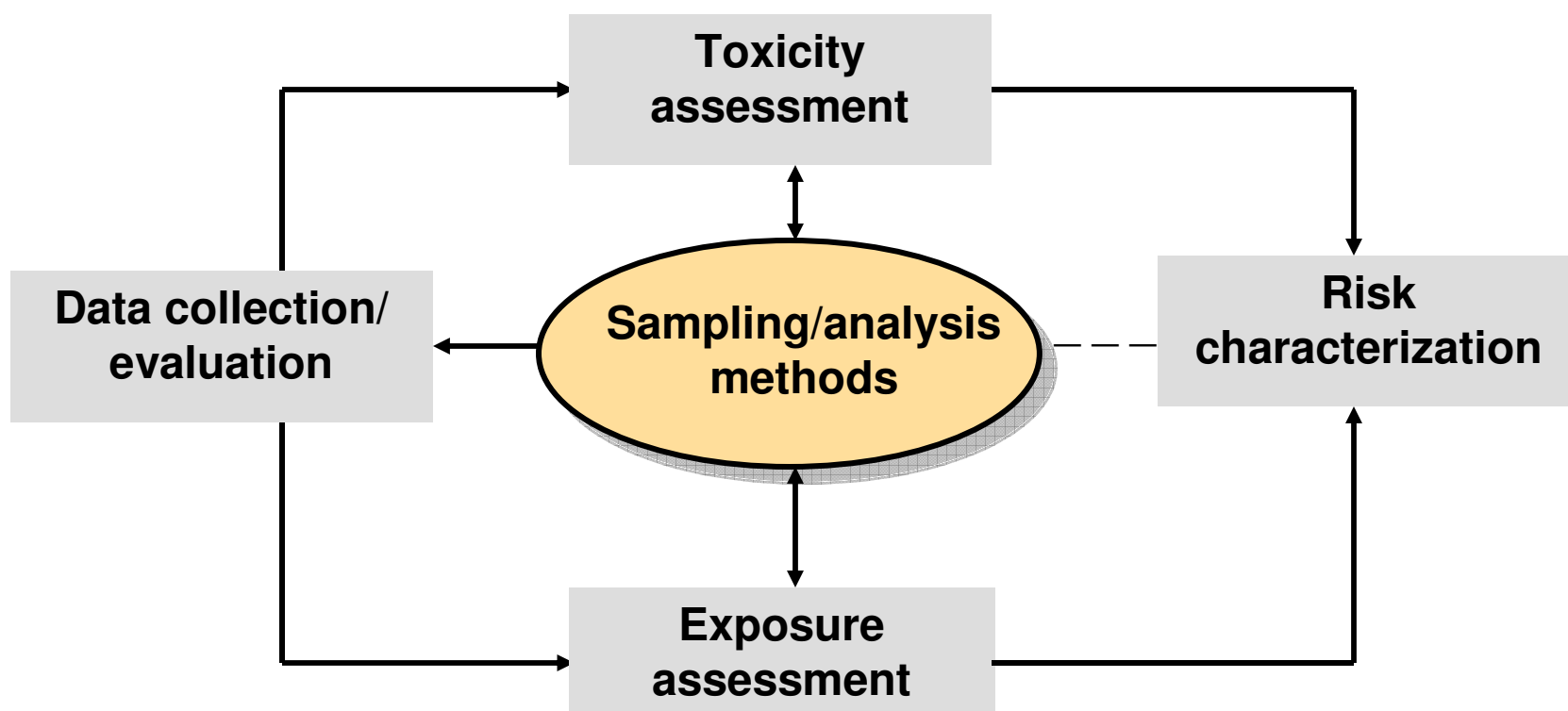 - Improve models of lung burden from air exposure (dosimetry)

Note: Any studies involving human research will be subject to prior review and approval by a qualified Human Subjects Review Board

Epidemiology

Sampling and Analytical Studies to Support Baseline Risk Assessment

Analytical

Sampling and Analysis

- Proposed research to improve knowledge of Libby Amphibole

  1. Filter studies

  2. Outdoor ambient air sampling verification

  3. Libby vermiculite fiber distribution

  4. Direct and indirect sample preparation comparison

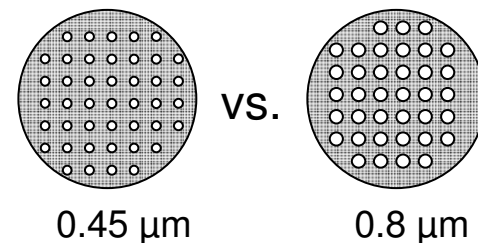 5. Low-level Libby Amphibole in soil method development
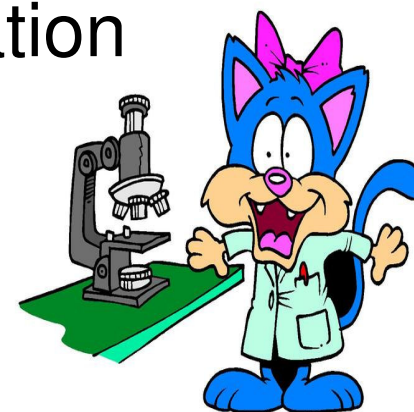
Analytical

1. Filter Studies

- Assess collection efficiency of Libby Amphibole related to filter pore size & filter composition
  - 0.45 μm vs. 0.8 μm pore size
  - Mixed Cellulose Ester vs. Polycarbonate filter material

0.45 μm   vs.   0.8 μm

- Questions we are asking
  - *Is there a loss of short fibers using the larger (0.8 μm) pore size filters?*
  - *Does one filter material collect Libby Amphibole sample more effectively?*

Analytical

2. Outdoor Ambient Air Sampling

- Perform "bench-scale testing" to evaluate sample collection efficiency of Libby Amphibole
  - Low air flow of known concentration
  - Collected continuously over several days
- Question we are asking
  - *If Libby Amphibole is present in outdoor ambient air, do we detect it?*

Analytical

3. Libby Vermiculite Fiber Distribution

- Characterize fibers generated in air from Libby vermiculite material

- Question we are asking
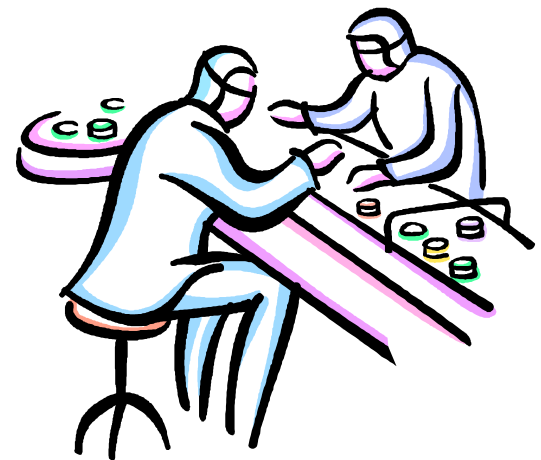 - *Are fibers generated similar to samples collected in Libby?*
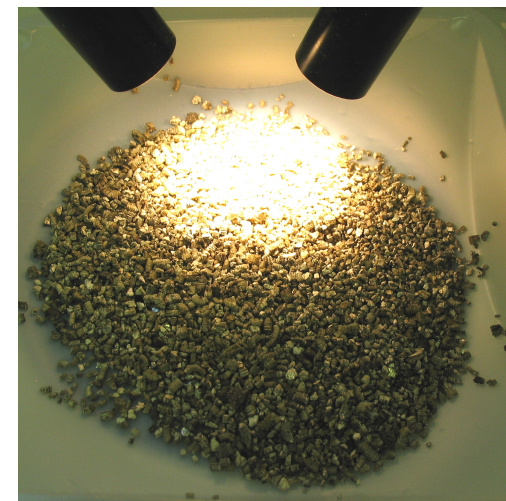
Analytical

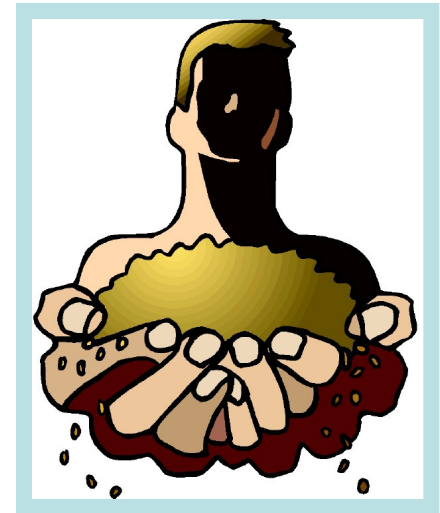# 4. Direct and Indirect Sample Preparation

- Compare methods
  - Direct prep = analysis of primary filter
  - Indirect prep = transfer of material from primary to secondary filter for analysis

- Question we are asking
  - *Do the different methods yield similar results?*
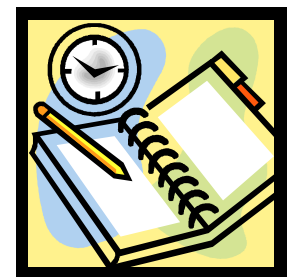
Analytical

5. Soil Method Development

- ## Test soils
  - With low levels of Libby Amphibole
  - Using EPA Region 10's "Glove Box" method

- ## Question we are asking
  - *Can the Glove Box method measure presence or absence of Libby Amphibole in soils at levels below 0.2%?*

Analytical

Analytical Timeline

- Research initiated in 2007
  - Filter studies
  - Outdoor ambient air sampling verification

- Research planned to initiate in 2008
  - Libby vermiculite fiber distribution
  - Direct & indirect sample preparation
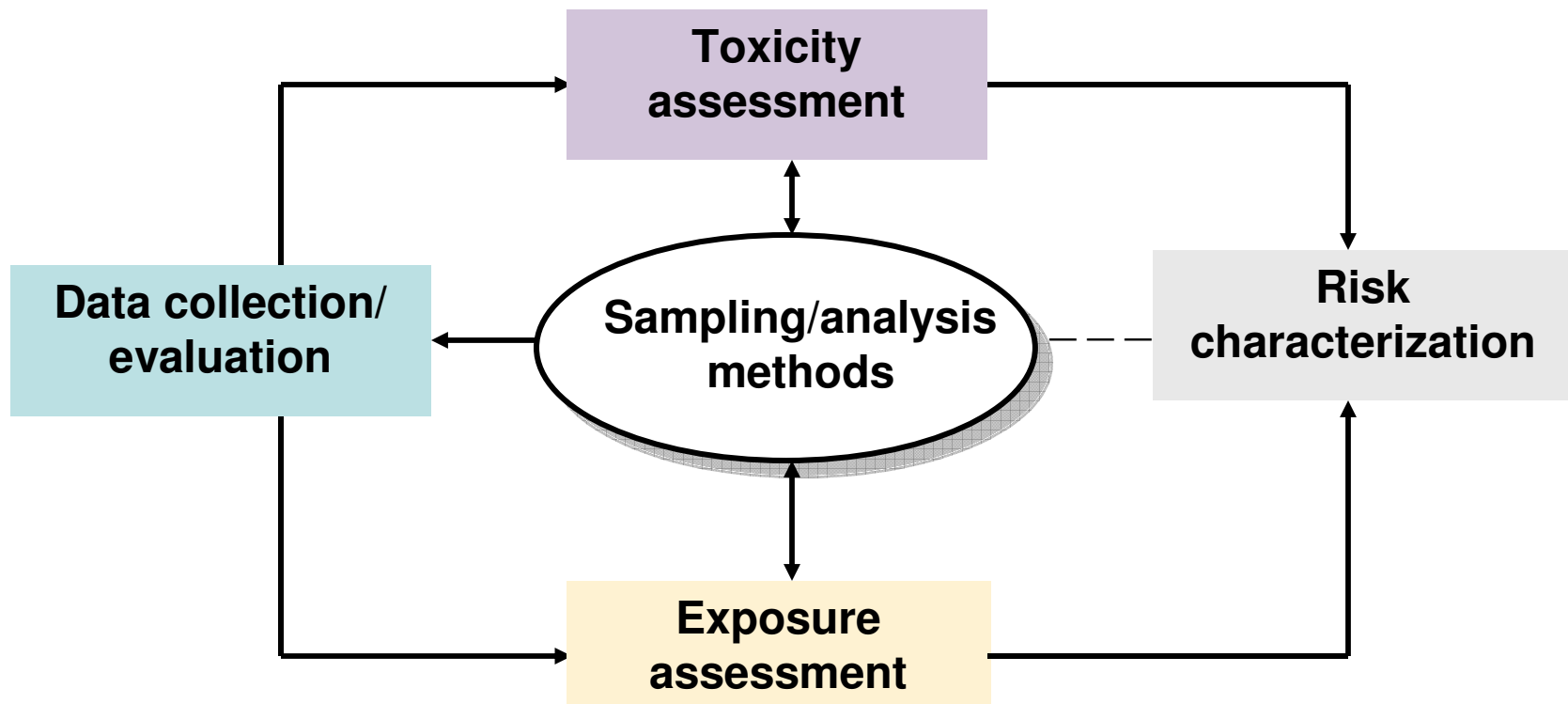 - Glove Box method validation

Analytical

Toxicity

From *The Montanian*, March 3, 2007

Baseline Risk Assessment

Human Health

Toxicity assessment

Data collection/ evaluation

Sampling/analysis methods

Risk characterization

Exposure assessment

Toxicity

Toxicity Data for Needed for BRA

1. Non-cancer health effects
2. Cancer risk
3. Mathematical models for estimating risk
4. Deposition of Libby Amphibole in lungs
5. Effects of Libby Amphibole in lungs and other tissues
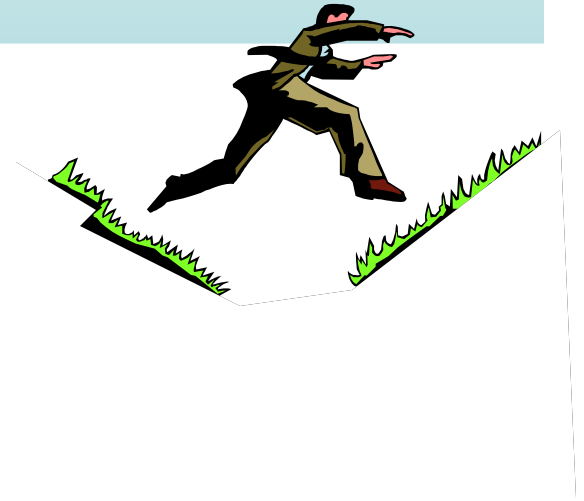
Toxicity

Toxicity Studies

Funded studies
- Ongoing Libby Amphibole RfC Development
- Libby Amphibole cancer assessment
- Preparation of Libby testing material
- Dosimetry model development & simulation studies
- In vitro dissolution assays
- Comparative toxicology in mice and rats
- Inhalation toxicology in rats
- New epidemiological information from Libby cohort
- New epidemiological information from other cohorts
- Ongoing OSWER Interim Cancer Risk Methodology

1. Non-Cancer Health Effects

- Reference Concentration (RfC)
  - *An estimate of the level in air at which continuous exposure to a substance over a lifetime is likely to be without appreciable risk of adverse health effects*
- No existing RfC for any type of asbestos
- Development of RfC for Libby Amphibole
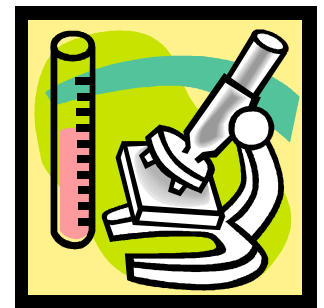 - Based on data from exposed workers in Marysville, Ohio

Toxicity

1. Non-Cancer Health Effects (cont.)

- Toxicity studies will focus on
  - Adverse effects in lungs and other tissues
  - How Libby Amphibole causes disease

- End results
  - Reduced uncertainty in development of RfC
  - More accurate risk assessment
 - More effective clean up

Toxicity

2. Cancer Risk

- Cancer Slope Factor (CSF)
  - Conservative estimate of increased cancer risk associated with lifetime exposure to a substance
- Current CSF for asbestos does ***not*** consider
  - Increased cancer potency of amphiboles
  - Short, thin fibers
  - Childhood exposures
  - Short duration, intermittent exposures
- CSF for Libby Amphibole will be developed

2. Cancer Risk (cont.)

- Toxicity studies will focus on
  - Relative potency of Libby Amphibole compared to other asbestos
  - Short, thin fibers
  - Early lifetime exposure
  - Intermittent, short-duration exposures
- End results
  - Reduced uncertainty in development of CSF
  - More accurate risk assessment
  - More effective clean up
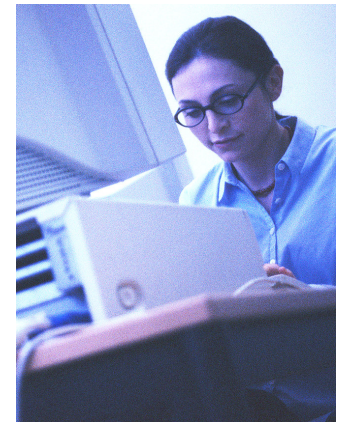
Toxicity

3. Mathematical Models for Risk

- ## OSWER Interim Cancer Risk Model
  - Effort led by EPA Office of Solid Waste and Emergency Response (OSWER)
  - Current draft undergoing revisions
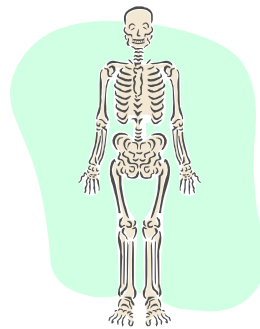 - Peer review and validation planned

Population-based data +

Toxicity

3. Mathematical Risk Models (Cont.)

- Physiologically Based Pharmacokinetic (preferably referred to as PBPK) Model
  - Long-term priority
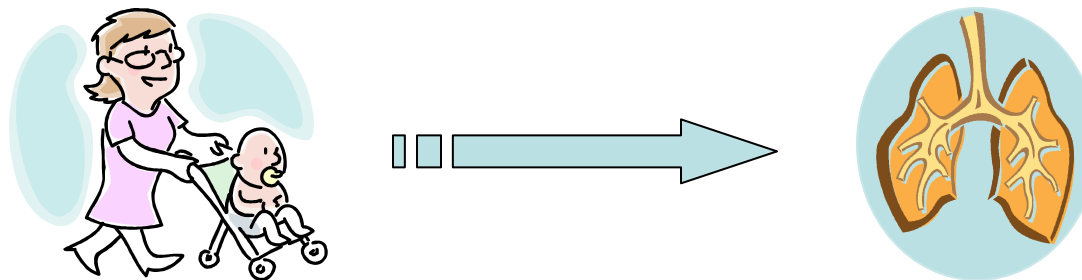 - Potentially useful for five-year review

Biologically-based data

+

Population-based data

Toxicity

4. Libby Amphibole in Lungs

- Amount in air versus amount in lungs
- Dosimetry modeling of exposure
  - How much actually gets into lungs?
  - What happens to it over time?
  - More accurate measure of exposure than amount in air

4. Libby Amphibole in Lungs (cont.)

- ## Exposure – Response relationship
  - Relationship between amount in lungs & disease
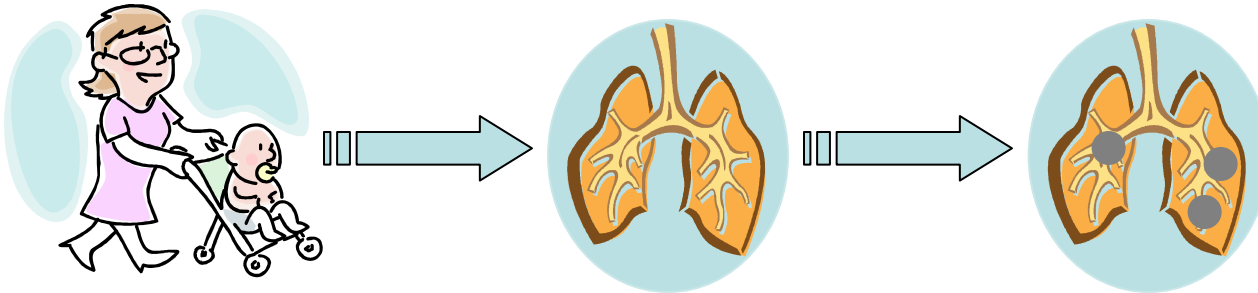
- ## End results
  - Improved scientific basis for evaluating exposure–response relationship
 - More accurate risk assessment
  - More effective clean up

5. Libby Amphibole in Lungs and Other Tissues

- Toxicity studies will improve understanding of adverse effects in lungs and other tissues
- Toxicity in other organs
  - Autoimmune disease
  - Chronic inflammation
  - Developmental/reproductive effects
- End results
  - Reduced uncertainty in development of RfC and CSFs
  - More accurate risk assessment
  - More effective clean up

Toxicity

In a nutshell....
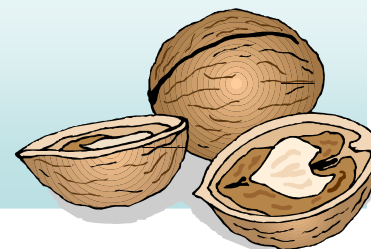
EPA's overall strategy is to

- Address critical Issues on the 4 OUs (residential/commercial, processing areas, the mine, and Troy)

- Define "How Clean is Clean" using exposure, epidemiology, laboratory analysis, and toxicity

As always, we welcome your questions (here or at the Info Center) and encourage your participation in the Community Advisory Group

THE
END

UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY